PREMARKET NOTIFICATION [510(k)] Summary

This Summary of Safety and Effectiveness is prepared in accordance with 21 CFR Part 807.92(c).

1. **Company Name:** BenQ Medical Technology Corporation
7F., No. 46, Zhou-Z St., Nei-Hu, Taipei 114, Taiwan

FEB 25 2014

Factory Location: Qisda Corporation
159 Shan-ying Road, Gueishan,
Taoyuan 333, Taiwan

Contact: Bob Leiker
Leiker Regulatory & Quality Consulting
7263 Cronin Circle
Dublin, CA 94568
Tel: (925) 719-1946 Fax: (866) 718-3819

2. **Device Name:** UP600 Diagnostic Doppler Ultrasound System with
C52 Curved Linear Array 2-5MHz,
L115 Linear Array 5-11MHz,
P42 Phase Array 80 elements 2-4MHz,
E94 Micro Convex Array 4-9MHz

Common/Usual Name: Diagnostic Ultrasound System with Accessories

Classification: Regulatory Class: II
Review Category: Tier II

Classification Name	21 CFR Section	Product Code
Ultrasonic pulsed doppler imaging system	892.1550	90-IYN
Ultrasonic pulsed echo imaging system	892.1560	90-IYO
Diagnostic ultrasonic transducer	892.1570	90-ITX

2. Marketed Devices:

Owner	Predicate Device	510(k) Number
BenQ Medical Technology	UP600	K121983
GE Healthcare	Voluson i	K053435
CGMC	OPUS 5000	K102989

3. Device Description:

The UP600 diagnostic doppler ultrasound system is a compact and portable diagnostic ultrasound device, have integrated preprogrammed color ultrasound imaging system, capable of producing a resolution intended for clinical diagnostic imaging applications. The user interface includes a specialized control keyboard and color 15-inch LCD display. The digital architecture with progressive dynamic receive focusing allows the system to maximize the utility of all imaging transducers to enhance the diagnostic utility provided by the system. The exam dependent default setting allows the user to have minimum adjustment for imaging the patient, while the in depth soft-menu control allows the advanced user to set the system for different situations. The architecture allows system integration to a variety of upgrade-able options and features.

The major features of the UP600:
128 Channel all digital beam former
Progressive dynamic receive focusing
Wide band all digital demodulation
Native resolution digital scan converter
Hand carried for portable use
USB2.0 flash drive for image transport and software upgrade
Supports 2D B-mode, M-mode, Harmonic Image, Color, Power Doppler, Pulse wave Doppler, and CW.

Intended Use:
The device is a general-purpose ultrasonic imaging instrument intended for use by a qualified physician for evaluation of Abdomen, Cardiac, Small Organ (breast, testes, thyroid), heart soft tissue, Peripheral Vascular, Musculo-skeletal (Conventional and Superficial), Pediatric, Fetal, Cephalic, and Ob/Gyn.

Technological Characteristics:
Display Modes:
Single and dual 2-D; Display of Duplex 2-D/M-mode; 2-D/Pulsed Doppler and Triplex 2-D/CD/Pulsed Doppler image formats; Dual B and Color in real time.

Measurements:
Distance; area; circumference; calipers; velocity, PI, RI. OB, Urology, Cardiac and Vascular package.

Principle of Operation
Applying high voltage burst to the Piezoelectric material in the transducer and detect the reflected echo to construct the 2-D B-mode, Doppler color, and Doppler spectrum image for diagnostic purposes.

The UP600 has been designed to meet the following product safety standards: NEMA UD 2, NEMA UD 3, IEC 60601-1, IEC 60601-1-2, IEC 60601-2-37, IEC 10993-1.

4. Indications for Use:

The device is a general-purpose ultrasonic imaging instrument intended for use by a qualified physician for evaluation of Fetal/OB; Abdominal (GYN & Urology); Pediatric; Small Organ (breast, testes, thyroid); Cardiac (adult & pediatric); Peripheral Vascular, Musculo-skeletal Conventional & Superficial, Transrectal and Transvaginal.

Comparison to Predicate Device:

The UP600 is of comparable type and substantially equivalent to both the GE Healthcare Voluson i, and the CGMC OPUS 5000. All systems transmit ultrasonic energy into patients, then perform post processing of received echoes to generate on-screen display of anatomic structures and fluid flow within the body, and have the same intended uses and basic operating modes as the predicate device. All systems allow for specialized measurements of structures and flow, and calculations.

Product Name 510(k) Number	Submission Device BenQ Medical Technology UP600 Pending	Predicate Device CGMC OPUS 5000 K102989	Predicate Device GE Voluson I K102989
Indications for Use	This device is a general-purpose ultrasonic imaging instrument intended for use by a qualified physician for evaluation of Abdomen; Pediatric; Small Organ (breast, testes, thyroid); heart soft tissue; Peripheral Vascular; Musculo-skeletal; Ob/Gyn and Urology.	Intended for use of evaluating Abdomen; Pediatric; Small Organ (breast, testes, thyroid); heart soft tissue; Peripheral Vascular, Musculo -skeletal and Urology.	Intended for use of evaluating Abdomen; Pediatric; Small Organ (breast, testes, thyroid); heart soft tissue; Peripheral Vascular, Musculo -skeletal and Urology.
Design	Based on 128 channel full digital beam former.	Based on 64 channel full digital beam former.	Based on a 128 channel full digital beam former.
Safety Compliance	IEC601-1 International Electrotechnical Comission; Medical Electrical Equipment IEC60601-2 International Electrotechnical Comission; Electromagnetic Compatibility	IEC601-1 International Electrotechnical Comission; Medical Electrical Equipment IEC60601-2 International Electrotechnical Comission; Electromagnetic Compatibility	IEC 60601-1 Electrical medical equipment, IEC 60601-1-1 Electrical medical equipment IEC 60601-1-2 Electromagnetic compatibility
Patient Contact Materials	RTV664+Ultrason S2010 silicon rubber complies with ISO10993-5	RTV664+Ultrason S2010 silicon rubber complies with ISO10993-5	GE RTV630A/B silicon rubber complies with ISO 10993-5
Operation Mode	B (2-D), M, CFM,CPA, PW, CW, Tissue Harmonic Image and combine mode	B, M, CFM, Power Doppler, PW, CW, Tissue Harmonic Image and combine mode	B-Mode (2D), M-Mode, M-Color-Mode, Color Flow Mode, Power Doppler Imaging, PW Doppler, Volume Mode (3D/4D):, 3D Static, 3D with Color Flow, 4D Real-Time
Display Modes	Single and dual 2-D; Display of Duplex 2-D/M-mode; 2-D/Pulsed Doppler and Triplex 2-D/CD/Pulsed Doppler image formats; Dual B and Color in real time	Single and dual 2-D; Display of Duplex 2-D/M-mode; 2-D/Pulsed Doppler and Triplex 2-D/CD/Pulsed Doppler image formats; Dual B and Color in real time	Real-Time Triplex Mode, Multi-image (split, quad)..Colorized Image, Time line display, Independent Dual B/PW Display,
Display Monitor	15" LCD color monitor	15" LCD color monitor	High-Resolution 15-inch TFT LCD Screen
Measurements	Distance; area; Volume; circumference; Heart Rate; calipers; velocity; PI, RI, Cardiac, OB/GYN and Vascular package.	Distance; area; Volume; circumference; Heart Rate; calipers; velocity; PI, RI, Cardiac, OB/GYN and Vascular package.	Obstetrics, Gynecology, Abdominal, Small-Parts, Vascular, Pediatrics, Urology, Ortho, Cardiology
Transducer Types & Connectors	Convex and Micro-convex (endo-cavity), Phase array, and Linear array probes, Multi-port connector connects up to 2 transducers	Convex, Phase array, Linear array, and Transvaginal Micro-Curved Linear probes, Multi-port connector connects up to 2 transducers.	Convex Array • Linear Array • Volume probes '4D' Convex Array • Volume probes '4D' Linear Array
Principle of Operation	Applying high voltage burst to the Piezoelectric material in the transducer and detect the reflected echo to construct the 2-D B-mode, Doppler color, and Doppler spectrum image for diagnostic purpose.	Applying high voltage burst to the Piezoelectric material in the transducer and detect the reflected echo to construct the 2-D B-mode, Doppler color, Doppler spectrum image for diagnostic purpose.	Applying high voltage burst to the Piezoelectric material in the transducer and detect the reflected echo to construct the 2-D B-mode, Doppler color, Doppler spectrum image for diagnostic purpose
Users / Sites	Hospitals, clinics usage	Hospitals, clinics usage	Hospitals, clinics usage
Acoustic Output	Track 3: MI, TIS, TIC, TIB Derated Ispta: 720mW/cm2 maximum, TIS/TIB/TIC:0.1-4.0 Range, Mechanical Index: 1.9 Maximum, or Derated Isppa: 190 W/cm^2 max	Track 3: MI, TIS, TIC, TIB Derated Ispta: 720mW/cm2 maximum, TIS/TIB/TIC:0.1-4.0 Range, Mechanical Index: 1.9 Maximum, or Derated Isppa: 190 W/cm2 max	Track 3: MI, TIS, TIC, TIB Derated Ispta: 720mW/cm2 maximum, TIS/TIB/TIC:0.1-4.0 Range, Mechanical Index: 1.9 Maximum, or Derated Isppa: 190 W/cm2 max
Labeling	Operator's Manual, brochure	Operator's Manual, brochure	Operator's Manual, brochure
Dimensions / Weight	Dimension: Height 36.1cm Width 36.3cm Depth 18.7cm Weight: 9kg	Dimensions Height 40 cm Width 40 cm Depth 20 cm Weight: 11kg	• Height: 59 mm (2.3 in) • Width: 358 mm (14.2 in) • Depth: 313 mm (12.4 in) • Weight (no peripherals): 11 lb (5kg)
Power Requirements	Power requirements: 100 Volts AC, 2.5 Amps 120 Volts AC, 2.1 Amps 230 Volts AC, 1.1 Amps 250 Volts AC, 1 Amps Power Consumption: 180 watts, max Operating temperature 5-40° C; relative humidity 10-80%;	Power requirements: 100 Volts AC, 3.3 Amps 120 Volts AC, 2.7 Amps 230 Volts AC, 1.4 Amps 250 Volts AC, 1.3 Amps Power Consumption 200 watts, max Operating temperature 15-40° C; relative humidity 10-90%;	Electrical Power • Voltage: 100 - 240 V, • Frequency: 50/60 Hz

5. Conclusion:

The UP600 is substantially equivalent in safety and effectiveness to the predicate systems. The systems are intended for diagnostic ultrasound imaging and fluid flow analysis. The systems have the same gray-scale. The systems have acoustic output levels below the applicable FDA limits. The systems are designed to applicable electrical and physical safety standards.

End of 510(k) Summary.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 25, 2014

BenQ Medical Technology Corporation/Qisda Corporation
% Mr. Bob Leiker
Leiker Regulatory & Quality Consulting (LRQC)
7263 Cronin Circle
DUBLIN CA 94568

Re: K132690
Trade/Device Name: UP600 Diagnostic Doppler Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, ITX
Dated: January 28, 2014
Received: January 30, 2014

Dear Mr. Leiker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

This determination of substantial equivalence applies to the following transducers intended for use with the UP600 Diagnostic Doppler Ultrasound System, as described in your premarket notification:

Transducer Model Number

C52 Curved Linear Array 2-5MHz	L115 Linear Array 5-11MHz
P42 Phased Array 80 elements 2-4MHz	E94 Micro Convex Array 4-9MHz

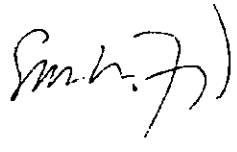
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page

510(k) Number *(if known)*

K132690

Device Name

UP600 Diagnostic Doppler Ultrasound System

Indications for Use *(Describe)*

The device is a general-purpose ultrasonic imaging instrument intended for use by a qualified physician for evaluation of Abdomen, Cardiac, Small Organ (breast, testes, thyroid), heart soft tissue, Peripheral Vascular, Musculo-skeletal (Conventional and Superficial), Pediatric, Fetal, Cephalic, Ob/Gyn, Trans-rectal, Trans-vaginal, Urology.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

System: UP600 Diagnostic Doppler Ultrasound System
Diagnostic Ultrasound Pulsed Echo System
Diagnostic Ultrasound Pulsed Doppler Imaging System

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Tissue Harmonic Imaging
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal	P	P	P		P	P	Note 1	P
	Abdominal	P	P	P		P	P	Note 1	P
	Intra-operative (Specify)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	P	P	P		P	P	Note 1	P
	Small Organ[1] (Breast, Thyroid, Testes)	P	P	P		P	P	Note 1	P
	Neonatal Cephalic	P	P	P	P	P	P	Note 1	P
	Adult Cephalic	P	P	P	P	P	P	Note 1	P
	Trans-rectal	N	N	N		N	N	Note 1	N
	Trans-vaginal	N	N	N		N	N	Note 1	N
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)	P	P	P		P	P	Note 1	P
	Musculo-skeletal (Superficial)	P	P	P		P	P	Note 1	P
	Intravascular								
	Other (Ob/GYN)	P	P	P		P	P	Note 1	P
Cardiac	Cardiac Adult	P	P	P	P	P	P	Note 1	P
	Cardiac Pediatric	P	P	P	P	P	P	Note 1	P
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel	P	P	P		P	P	Note 1	P
	Other (Specify)								

N = new indication; P = previously cleared by FDAE = added under this appendix
Note 1: Combined includes: B/M; B/PWD; B/Color Doppler; B/Power Doppler; B/Color Doppler/PWD and B/Power Doppler/PWD

Prescription Use____X_____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

System: UP600 Diagnostic Doppler Ultrasound System
C52 Curved Linear Array 2-5MHz
Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Tissue Harmonic Imaging
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal	P	P	P		P	P	Note 1	P
	Abdominal	P	P	P		P	P	Note 1	P
	Intra-operative (Specify)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	Small Organ[1] (Breast, Thyroid, Testes)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)	P	P	P		P	P	Note 1	P
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel								
	Other (Specify)								

N = new indication; P = previously cleared by FDA E = added under this appendix
Note 1: Combined includes: B/M; B/PWD; B/Color Doppler; B/Power Doppler; B/Color Doppler/PWD and B/Power Doppler/PWD

Prescription Use___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

System: UP600 Diagnostic Doppler Ultrasound System
L115 Linear Array 5-11MHz
Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Tissue Harmonic Imaging
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal								
	Intra-operative (Specify)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	Small Organ[1] (Breast, Thyroid, Testes)	P	P	P		P	P	Note 1	P
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)	P	P	P		P	P	Note 1	P
	Musculo-skeletal (Superficial)	P	P	P		P	P	Note 1	P
	Intravascular								
	Other (Ob/GYN)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel	P	P	P		P	P	Note 1	P
	Other (Specify)								

N = new indication; P = previously cleared by FDA E = added under this appendix
Note 1: Combined includes: B/M; B/PWD; B/Color Doppler; B/Power Doppler; B/Color Doppler/PWD and B/Power Doppler/PWD

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

System: UP600 Diagnostic Doppler Ultrasound System
P42 Phased Array 80 elements 2-4MHz
Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Tissue Harmonic Imaging
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal	P	P	P	P	P	P	Note 1	P
	Intra-operative (Specify)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	Small Organ[1] (Breast, Thyroid, Testes)								
	Neonatal Cephalic	P	P	P	P	P	P	Note 1	P
	Adult Cephalic	P	P	P	P	P	P	Note 1	P
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)								
Cardiac	Cardiac Adult	P	P	P	P	P	P	Note 1	P
	Cardiac Pediatric	P	P	P	P	P	P	Note 1	P
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel								
	Other (Specify)								

N = new indication; P = previously cleared by FDA E = added under this appendix
Note 1: Combined includes: B/M; B/PWD; B/Color Doppler; B/Power Doppler; B/Color Doppler/PWD and B/Power Doppler/PWD

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

System: UP600 Diagnostic Doppler Ultrasound System
E94 Micro Convex Array 4-9MHz
Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Tissue Harmonic Imaging
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal								
	Intra-operative (Specify)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	Small Organ[1] (Breast, Thyroid, Testes)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal	N	N	N		N	N	Note 1	N
	Trans-vaginal	N	N	N		N	N	Note 1	N
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)	N	N	N		N	N	Note 1	N
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel								
	Other (Specify)								

N = new indication; P = previously cleared by FDA E = added under this appendix

Note 1: Combined includes: B/M; B/PWD; B/Color Doppler; B/Power Doppler; B/Color Doppler/PWD and B/Power Doppler/PWD

Prescription Use____X_____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)